Standards Update
What's New and What's Next

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Standards Published Since the Last Year's Bethesda Interchange

Foundational Standards

- SDTM v1.7
- SDTMIG v3.3
- SDTMIG-Medical Devices v1.1
- ADaM Conformance Rules v2.0
- Define.XML v2.1
- SENDIG Animal Rule v1.0
- SDTM v1.8

Therapeutic Area Standards

- HIV
- PTSD
- Colorectal Cancer
- Huntington's Disease
- CDAD
- Lung Cancer
- Traditional Chinese Medicine – CAD-Angina
- Nutrition

Publishing Soon!

- ADaMIG v1.2
- CDASHIG 2.1
- CDASH Model v1.1

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New Onboarding Process for Volunteers

- Single internal point of contact for onboarding, administrative and record updates, to ensure accurate follow-up of volunteers

- Leveraging of IT tools to facilitate communication and teamwork

- Improved processes and procedures to support volunteer activities

CDISC Staff Support for Foundational Teams

- Project Management Support
  - Scope planning
  - JIRA project management
  - Wiki support
  - Navigating the CDISC governance process
- Allows teams to focus on standards development

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Codetable Mapping Files

- Built to show explicit relationships between terms in different codelists
- Machine-readable, published on CDISC website
- DS, CV, EG, TU/TR/RS (Oncology) Race/Ethnicity, SC, TS, VS
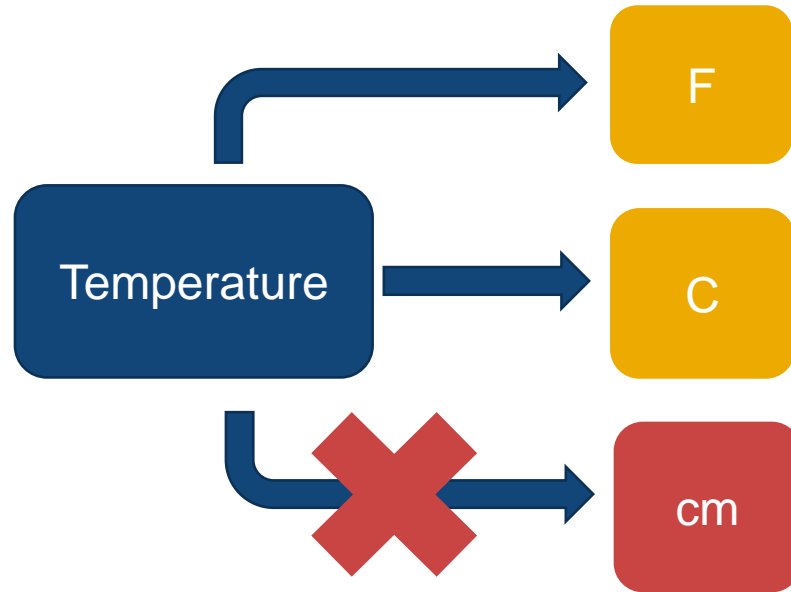
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LOINC-CDISC Mapping

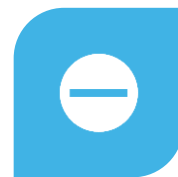CDISC CT TEAM HAS COMPLETED THE LOINC-CDISC LB MAPPING

CONTAINS APPROXIMATELY 2,000 LB MAPPINGS

REVIEW BY THE REGENSTRIEF INSTITUTE AND FDA LOINC WORKING GROUP COMPLETE

POSTED FOR INTERNAL REVIEW IN AUGUST 2019

MAPPING WILL BE RELEASED FOR PUBLIC COMMENT SOON

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UCUM Codelist Table

- A codelist table that allows users to toggle between UCUM and CDISC Unit codelists

- For each published CDISC submission value across all UNIT-based codelists in SDTM terminology, the mapping provides valid UCUM expressions associated with that unit concept

- Allows for a collected UCUM-compliant unit of measure to be easily matched to the appropriate CDISC submission value associated with that concept

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What Are We Working on Now?

Foundational Standards in Development

Conformance Rules	SDTM v2.0	SENDIG v3.1.1	ADaM OCCDS v1.1
ADaM Data Structures for Integration	SDTMIG v3.4	SDTM Variable Definitions	Multiple QRS and ADQRS Supplements

CDASH-SAE Supplement

https://www.cdisc.org/standards/in-development

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Therapeutic Area User Guides Currently In Development

Type 1 Diabetes · Crohn's Disease · Acute Kidney Injury · Psoriasis · Heart Failure · TCM Acupuncture · Pancreatic Cancer

https://www.cdisc.org/standards/in-development
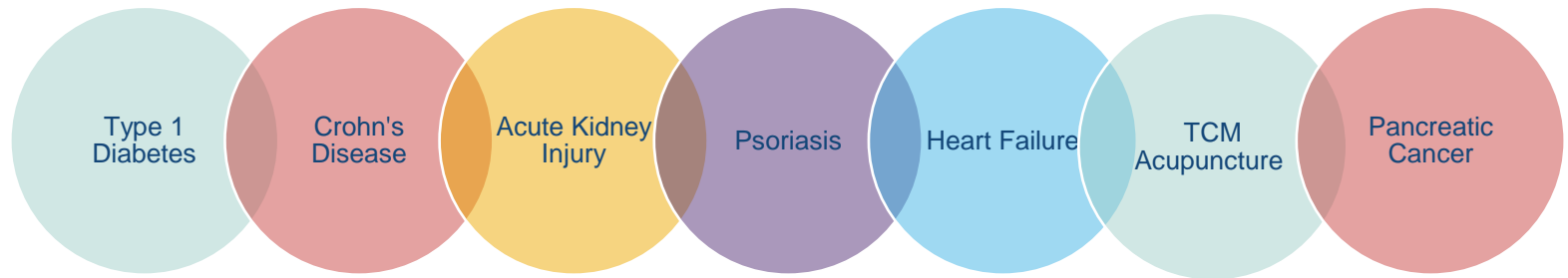
CDISC Knowledge Base Project

An open, assessible, searchable
and user-friendly interface on
the CDISC Website to host new and
existing website content for
CDISC implementers

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Knowledge Base – Project Components

Coordinated with redeveloped standards website pages

CDISC-generated content - technical articles written by CDISC staff and teams

Community-generated content, curated by CDISC

Community questions, with curated CDISC team answers

Links to external useful content

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Publication of Errors and Known Issues

Errors

- Small errors such as typos that do not affect conformance
- Errors that affect conformance

Known Issues

- Inconsistencies within a CDISC standard
- Inconsistencies between standards
- Inconsistencies between a CDISC standard and regulatory agency advice
- Gaps in standards

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Publication of Errors and Known Issues

Provide possible solutions

Vetted and approved by the CDISC Global Governance Group

Will be made available in real-time to the user community

Occurrence of one of a group of Events or Interventions

Affected Standard	SDTMIG v3.3 and earlier
Data to be represented	A finding of the form "Did an <event or intervention in this group> occur?"
Reason for uncertainty	Occurrence questions at the level of a domain (e.g, "Did the subject take any concomitant medications?" or "Did the subject have any adverse events?") can be represented in CDASH, but are not included in SDTM datasets.
	Occurrence questions at the level of a specific event or intervention are represented in an events or interventions domain in a record with the specific event or intervention in the topic variable --PRESP = "Y" and the response to the question in ("Y" or "N") in --OCCUR.
	No guidance is given about questions at an intermediate level, although such questions are common. For example, "Has the subject taken any opiate-containing medications?" or "Has the subject had any respiratory infections?"
Possible solution for affected version(s)	The Therapeutic Area User Guide for Asthma represented questions about groups of medications in a CM record with both CMTRT and CMSCAT equal to the name of the group (e.g., "SHORT-ACTING BETA-AGONISTS" or "SYSTEMIC CORTICOSTEROIDS") and CMPRESP = "Y". The fact that the value in CMTRT is equal to the value in CMSCAT indicates that the question is about a group of concomitant medications.
	This convention, of populating both the topic variable and either --CAT or --SCAT with the name of the group, can be used as a solution with current versions of the SDTMIG. Whether --CAT or --SCAT is used depends on whether --CAT is available or is being used for another purpose. The use of this convention should be explained in the Clinical Study Data Reviewers Guide (cSDRG).
Efforts to resolve issue	This convention is being considered for inclusion in a future version of the SDTMIG. It has been logged as a JIRA issue: https://jira.cdisc.org/browse/SDS-26

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Curated Non-Standard Variable Registry

Enables consistency in the absence of a standard variable

Will contain all non-standard variables used in CDISC Implementation and User Guides

Vetted by the CDISC Global Governance Group

Will be made available in real-time to the user community
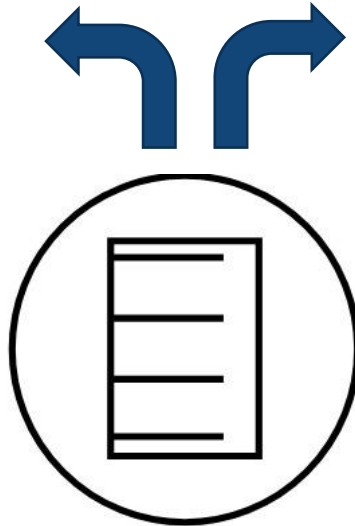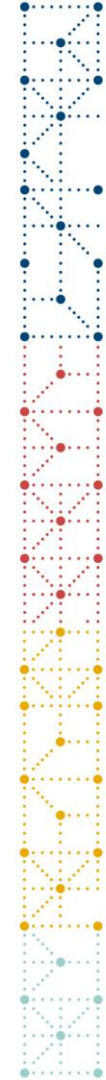
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Consideration Documents for Regulatory Requirements
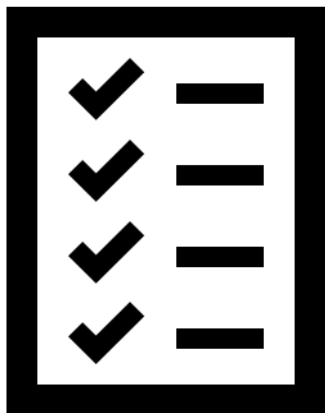
Race and ethnicity

QRS logically skipped items

Representation of SI and conventional units
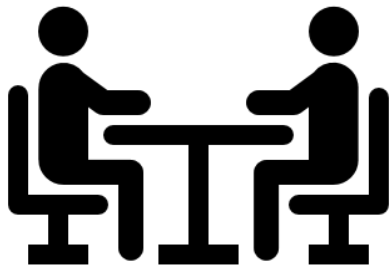
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SDTM Reorganization

Update outdated language

Move domain-specific variables

Make metadata consistent and separated

- Definitions will be added, and definition-like material will be removed from description column

Will be published in November 2020 as SDTM v2.0

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Development of Principles

Guides and improves understanding of the standard

Facilitates decision making

Helps to optimize utilization of resources

Helps to manage change
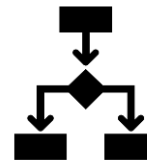
Principles Hierarchy

Accomplish the CDISC goals and mission without promoting any individual vendor or organization

Manage scope with incremental development

Start with the end in mind

Domain variables based on the same root variable have the same meaning in all domains

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Update of Metadata Submission Guidelines Package

Current package enables users to become familiar with the SDTM submission components

Contains annotated CRF, submission datasets, define.xml file, define.xml stylesheet, and Reviewers' Guide

Cross team collaboration

Goal is to publish update as soon as possible

Conformance Rules

- CDISC authors rules that determine conformance with the standard by version of standard

- Regulatory agencies have their own rules specific to their needs, these may or may not be the same as CDISC authored conformance rules

- Historical development of rules
  - Standards were written before the rules which led to ambiguity
  - The guides were specific to a team and standard

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Future of Conformance Rules

RULES ARE NOW REQUIRED AT THE TIME OF PUBLICATION OF ANY STANDARD

WORKING ON ESTABLISHING CROSS-TEAM RULES DEVELOPMENT METHODS

SUPPORTED BY CDISC LIBRARY

Redesigned Conformance Rules

Variable Name	Variable Label	Data Type	Controlled Terms	Codelist	Codelist Subset	Format	Role / Variable Group	Definition	Associated Example(s)	Associated Assumption(s)	Implementation Guidance	Supporting Note(s)	Variable Presence	Variable Presence Condition	Value Presence	Value Presence Condition	CR ID
STUDYID	Study Identifier	Char					Identifier	Unique identifier for a study.					Required		Required		01.0011
DOMAIN	Domain Abbreviation	Char		DM			Identifier	Two-character abbreviation for the domain.					Required		Required		01.0012
USUBJID	Unique Subject	Char					Identifier	Identifier used to uniquely identify a subject across all studies for all applications...		2	This must be a unique number, and could be a compound identifier formed by concatenating STUDYID-SITEID-SUBJID.		Required		Required		01.0013
SUBJID	Su... Ide... the...																01.0014

Clear and transparent conformance rules

Clear and transparent associations (assumptions, examples, etc.)

A catalog of cross-standard conformance rules

Investigator and site identification: Companies use different methods to distinguish sites and investigators. CDISC assumes that SITEID will always be present, with INVID and INVNAM used as necessary. This ... XML document.

2. Every subject in a study must have a subject identifier (SUBJID). [01.0014] In some cases a subject may participate in more than one study. To identify a subject uniquely across all studies for all applications or ... datasets. Subjects occasionally change sites during the course of a clinical trial. The sponsor must decide how to populate variables such as USUBJID, SUBJID and SITEID based on their operational and analy... Supplemental Qualifiers dataset may be used if appropriate to provide additional information.

3. Concerns for subject privacy suggest caution regarding the collection of variables like BRTHDTC. This variable is included in the Demographics model in the event that a sponsor intends to submit it; however, sp...

4. With the exception of trials that use multi-stage processes to assign subjects to Arms described below, ARM and ACTARM must be populated with ARM values from the Trial Arms (TA) dataset and ARMCD and... The ARM and ARMCD values in the TA dataset have a one-to-one relationship, and that one-to-one relationship must be preserved in the values used to populate AR...

  a. Rules for the Arm-Related Variables:

    i. If ARMCD is null, then ARM must be null and ARMNRS must be populated with the reason ARMCD is null. [02.0044]

    ii. If ACTARMCD is null, then ACTARM must be null and ARMNRS must be populated with the reason ACTARMCD is null. Both ARMCD and ACTARMCD will be null for subjects who were not assigned...

    iii. ARMNRS may not be populated if both ARMCD and ACTARMCD are populated. ARMCD and ACTARMCD will be populated if the subject was assigned to an arm and received treatment consistent... that is sufficient to explain the situation: ARMNRS should not be populated.

Conformance Rule Version Association	Unique Conformance Rule ID	Conformance Rule URI	Rule Level Association	Rule Explanation	Rule Categorization
SDTMIG.v3.3.CR.v1.0	01.0011	SDTMIG.v3.3.CR.v1.0.01.0011	Variable	STUDYID = DM.STUDYID	Error
SDTMIG.v3.3.CR.v1.0	01.0012	SDTMIG.v3.3.CR.v1.0.01.0012	Variable	DOMAIN = valid Domain Code published by CDISC	Error
....	....	....	....	....	....
SDTMIG.v3.3.CR.v1.0	05.0009	SDTMIG.v3.3.CR.v1.0.05.0009	Domain	Example explanation for domain level rules.	Warning

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Disclaimer: This is only a proposed draft snapshot.

Curated Examples

- Examples exist across many Implementation and User Guides in PDFs

- Goal is to make examples accessible through CDISC Library

- Users will be able to select examples by biomedical concept, therapeutic area, observation class, domain etc.

- Curation to ensure examples remain consistent with one another

- Initial scope: Diabetes v1.0, Diabetic Kidney Disease v1.0, Type 1 Diabetes v1.0

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Curated Examples

Disclaimer: This is only a proposed draft snapshot.

Thank you!